

**PSJ4 SOL Opp App A Exh 11**

LAW OFFICES  
**HYMAN, PHELPS & McNAMARA, P.C.**

JOHN A. GILBERT, JR.

700 THIRTEENTH STREET, N.W.  
SUITE 1200  
WASHINGTON, D. C. 20005-5929  
(202) 737-5500  
FACSIMILE  
(202) 737-9329  
www.hpm.com

Direct Dial (202) 737-4293

April 25, 2007

**BY FACSIMILE/CONFIRMATION COPY BY MAIL**

Linden Barber, Esq.  
Associate Chief Counsel  
Office of Chief Counsel  
Diversion and Regulatory Litigation Section  
Drug Enforcement Administration  
600 Army/Navy Drive  
Arlington, Virginia 22202

Dear Mr. Barber:

This is to follow-up on the meeting that Doug Farquhar and I had with you and Wayne Patrick on April 5, 2007 in regard to the Order to Show Cause pending against McKesson Corporation's Lakeland, Florida Distribution Center (DC). We appreciate your willingness to discuss a possible settlement agreement to this matter and are hopeful that an agreement can be reached.

I trust we were able to convey that McKesson is committed to compliance with all DEA requirements. The task of identifying suspicious orders related to pharmacies dispensing medicine outside the legitimate course of medicine is particularly challenging for wholesale distributors like McKesson. There is no one formula or set of criteria that can be used for all customers. You have shared some of DEA's experience in this area that McKesson has incorporated into its program. That said, it will take cooperation between DEA and the regulated industry to maintain an ongoing system to identify pharmacies operating outside legitimate medical practice.

In the last two years, McKesson, at the Lakeland DC as well as all other DCs, has increased its monitoring and awareness of customers who may be ordering controlled substances in amounts not consistent with legitimate medical practice. McKesson has supplied DEA with information about questionable companies and has responded to DEA subpoena requests in a timely manner. McKesson has also taken immediate action to

2503 MAIN STREET  
SUITE 750  
IRVINE, CALIFORNIA 92614  
(949) 553-7400  
FAX: (949) 553-7433

4910 EMERSON BOULEVARD  
SUITE 400  
DURHAM, NORTH CAROLINA 27703  
(919) 313-4750  
FAX: (919) 313-4751

Linden Barber, Esq.  
April 25, 2007  
Page 2

HYMAN, PHELPS & McNAMARA, P.C.

terminate any customer identified by DEA as subject to a show cause or other enforcement action.

#### **Proposed Action Plan**

We agree that it is in McKesson's interest to implement a program across all of its DCs that can assist the company in identifying potential excessive purchases and enable the company to work more closely with DEA. Thus, McKesson is taking the following steps, which we propose as the basis to resolve the Lakeland Show Cause and ensure that all McKesson DCs reduce the potential for excessive pharmacy purchases.

##### **A. Lifestyle Drug Monitoring Program**

In addition to the procedures McKesson employs to identify suspicious orders for controlled substances, McKesson is implementing a Lifestyle Drug Monitoring Program (LDMP) for certain controlled substances. Some of the actions identified below have already been implemented in the DCs. However, all of these steps will be in place by May 1, 2007, except as noted below. The LDMP will operate as follows:

1. The program will include all pharmacy orders of "lifestyle drug" controlled substances. The current list of lifestyle drugs which McKesson has programmed into this system are: oxycodone, hydrocodone, alprazolam and phentermine. Any drug products containing one of these substances will be subject to the monitoring program. Other drugs can be added to this list as necessary.

2. Each McKesson DC will produce a *Daily Dosage Summary Report*. McKesson's corporate information technology (IT) department has spent several months developing the technology that will enable each McKesson DC to generate this automated report to identify threshold sales. The report will identify all registrants/customers that have met or exceeded the monthly dosage threshold for lifestyle drugs.

3. McKesson has established the current monthly threshold for lifestyle drugs at 8,000 dosage units. Based on a review of all McKesson pharmacy accounts and relying on estimates provided by DEA, this amount appears to be a conservative yet realistic threshold to begin the program.

4. When a pharmacy customer appears on the report for the first time (because they have met or are about to exceed 8,000 dosage units for the month) the DC will review the orders to determine whether it is justified based on the type of customer, e.g., national chain account, and the historical purchases by the customer. If there are still

Linden Barber, Esq.  
April 25, 2007  
Page 3

HYMAN, PHELPS & McNAMARA, P.C.

questions, the customers will not be allowed to exceed the 8,000 monthly dosage limit until a due diligence review has been completed. The DC operations and regulatory staff will conduct a review of these accounts which will include contacting the customer to determine the basis for the request to exceed the monthly limit.

5. The McKesson DC management or regulatory staff, where appropriate, will conduct a further review to verify information provided by its customers. For example, if a pharmacy claims that it is receiving increased prescriptions from a pain clinic, McKesson will attempt to verify such information with the clinic as well as request further documentation that the clinic is issuing prescriptions in the course of legitimate medical practice.

6. The McKesson DC will require a signed affidavit from any customer that has been subject to an additional review to include documentation of the reasons to exceed the threshold and an affirmation from the customer that it has ascertained and verified that the controlled substances prescriptions that they dispense are from practitioners who have issued the prescriptions in the course of a legitimate medical practice, e.g., pursuant to a physical examination.

7. McKesson will terminate any account where it cannot adequately justify the request to purchase in excess of 8,000 dosage forms per month. McKesson will also submit a written report to the local DEA on the results of any due diligence review where a customer is unable to verify the basis for an order that exceeds the threshold or where McKesson receives other information that indicates that a customer is not dispensing for a legitimate medical purpose. This reporting is in addition to McKesson's current procedures for reporting Suspicious Orders.

8. McKesson will maintain records of customers that have been authorized to exceed the monthly thresholds and document the basis for such decisions. This authority will be reviewed on an ongoing basis by the DC operations and regulatory staff and periodically reviewed by corporate regulatory staff.

9. McKesson has created a new Program Analyst position, who will report to corporate senior management responsible for distribution operations and regulatory compliance. This person will participate in ensuring that the reviews described above are properly conducted and documented, and will be responsible for reviewing information from each DC regarding distribution of controlled substances. This person will also conduct research on Internet dispensing and transmit periodic reports to the DCs on companies or practices that have been identified as potential problems.

Linden Barber, Esq.  
April 25, 2007  
Page 4

HYMAN, PHELPS & McNAMARA, P.C.

10. At the end of every month, each McKesson DC will generate a *Monthly Dosage Report* that will include all accumulated dosage units for registrants/customers who at any time during the month exceeded the threshold. McKesson will use this report to conduct a further review of possible excessive orders. For example, McKesson will conduct a review of any account whose total orders of controlled substances are a large percent (based on metrics identified by McKesson consistent with its pharmacy customers) of their total monthly order for prescription drugs. The customer will be subject to the same due diligence and review process as discussed above.

11. McKesson has scheduled additional training for its ARCOS staff so that these staff can also identify potential issues and report them to the DC Manager.

12. Written notification of this program will be sent to all current McKesson pharmacy customers by June 1, 2007 and the program will be a mandatory part of the business relationship with new pharmacy accounts.

13. All of the daily or monthly reports will be made available to DEA. McKesson will submit these reports or records to DEA if requested.

#### **B. Industry Conference**

McKesson will financially support an industry conference facilitated by a third party such as the Healthcare Management Distribution Association (HDMA) to educate the regulated industry, wholesalers and pharmacies on the appropriate procedures for monitoring and reporting suspicious orders for these and all controlled substances. The focus will be on sales to pharmacies and development of procedures to identify potential orders for controlled substances that may not be dispensed for legitimate medical purposes. We propose to use the McKesson plan as a model and the basis for forming an industry task force to work with DEA to reduce the problem of unlawful prescribing. We expect that about 300 attendees will participate in the conference without paying an admission fee (although lodging, travel, and food expenses will be the responsibility of the attendees). The attendees will include representatives from wholesaler distribution operations; regulatory management; DEA headquarters; regional group supervisors and retail chain regulatory management.

The objective of the conference would be to adopt recommendations for best practices for identification of excessive orders and of dispensing outside the course of legitimate practice. We expect the conference to cost in excess of \$50,000.



Linden Barber, Esq.  
April 25, 2007  
Page 5

HYMAN, PHELPS & McNAMARA, P.C.

**Accounts Referenced at April 5, 2007 Meeting**

You raised questions about three McKesson accounts: NewCare, Smeeta and MediPharm at our meeting. We wanted to make sure, at a minimum, that these concerns were addressed. We discussed these accounts with the company and all of these accounts were previously terminated. The following is additional information on McKesson's investigation of these accounts.

Newcare Pharmacy had been a McKesson customer since 1993; the account was closed in October 2006. Based on McKesson's records, McKesson first discussed this account with Don Tush, of the DEA Baltimore office on October 27, 2005. McKesson submitted information to DEA at that time pursuant to an administrative subpoena. In February 2006, McKesson significantly reduced further sales to this customer and requested that the pharmacy provide additional justification for its orders. The pharmacy claimed to have added nursing home accounts. On February 27, 2006, McKesson contacted Mr. Tush on whether to keep selling to this customer in light of DEA's investigation. McKesson made this inquiry in light of the fact that the administrative subpoena warned McKesson not to divulge the existence of the investigation to any other party. DEA stated that it could not advise McKesson on what to do. Nevertheless, on March 20, 2006, McKesson limited this account to daily orders of a maximum of 4 bottles of hydrocodone.

In regard to Smeeta Pharmacy, on August 23, 2006, McKesson identified high volumes of purchases by this pharmacy for phentermine and Adipex P. McKesson sent an inquiry to Smeeta immediately requesting justification for the increased orders. Smeeta responded that they had added several weight loss clinic customers. McKesson requested additional information from Smeeta several weeks later. In October 2006, the local DEA office (DI Stevenson-Maye) issued an administrative subpoena to McKesson for records of these orders. McKesson promptly responded. At the end of October 2006, McKesson contacted DI Stevenson-Maye to advise DEA that McKesson was cutting Smeeta's orders and asked for clarification if this action would hinder DEA's investigation. DEA responded that cutting the orders would not interfere with DEA's investigation but she could not advise McKesson on cutting the orders. McKesson cut back the orders to Smeeta by 90 percent. The account was terminated in February 2007 as a result of Smeeta's immediate suspension.

Finally, the Lakeland DC suspended shipments of hydrocodone to MediPharm in Tampa, Florida in January 2006. MediPharm maintained two state licenses and two DEA registrations at the pharmacy. One state license/DEA registration was for general dispensing and this is the DEA registration that DEA identified to McKesson as of concern

Linden Barber, Esq.  
April 25, 2007  
Page 6

HYMAN, PHELPS & McNAMARA, P.C.

for large purchases of hydrocodone. McKesson terminated sales to MediPharm for this registration in January 2006 and did not make further sales to this account. However, MediPharm's second state license/DEA registration was for dispensing medicine for nursing homes. The volume of controlled substances order by this account was very small and consistent with sales to long-term care facilities. This is the MediPharm account to which McKesson sold small amounts of hydrocodone in October 2006.

#### **Suspension of Sales**

In our discussion, you raised the issue of a possible suspension of hydrocodone sales at the Lakeland DC and phentermine at the Landover DC as part of a plan to resolve the Show Cause matter. We would like to discuss this matter with you in more detail, however, we believe the actions discussed above will ensure that the Lakeland, Landover and other McKesson DCs will be able to appropriately guard against and prevent sales to pharmacies that may not be dispensing medicines for legitimate prescriptions. More important, suspending sales of controlled substances from these facilities will have significant adverse impact on the delivery of prescription drugs and on McKesson's customers that are not involved in the unlawful dispensing.

First, the Lakeland DC is one of only two McKesson DCs, the other being a back-up in Ohio, that are capable of producing the documentation required to meet the electronic drug pedigree requirements in Florida. The pedigree regulations require that distributors provide pedigree papers documenting all prior transactions involving a prescription drug. The Lakeland DC is handling an increased volume of sales from McKesson customers covering a wider geographic area. This includes orders for controlled substances, e.g., hydrocodone. A blanket suspension of the ability of Lakeland to process hydrocodone would make it difficult for McKesson to provide the appropriate pedigree for transactions involving products distributed into and out of Florida.

Second, the Lakeland and Landover DCs distribute drug products including controlled substances to numerous healthcare accounts including hospitals and government facilities (such as VA hospitals), and these DCs provide drug products to other McKesson subsidiaries that sell to practitioner offices. Thus, all of these healthcare entities rely on the DCs for pain medicine, particularly hydrocodone. Also, McKesson currently has a number of contractual commitments with large pharmacy chain customers such as Target, CVS and Rite Aid. None of these customers is a source of the problem identified by DEA involving dispensing of lifestyle drugs without appropriate prescriptions. However, these contracts contain specific performance measures, particularly, requiring delivery of needed medicines within strict timeframes. There are significant financial penalties associated with service failures which would result from restriction on distribution of certain products.

Linden Barber, Esq.  
April 25, 2007  
Page 7

HYMAN, PHELPS & McNAMARA, P.C.

Several national chain and hospital customers make up a large percentage of both Lakeland's and Landover's business.

Third, the ability to service these accounts from the other DCs may not be feasible without unnecessarily creating contract violations or reducing the level of service. There is also the obvious financial impact, but it is the long-range effect on the business and customer relations that would be the major issue. Sourcing through another DC, even if possible, would burden other McKesson DCs, increase operating costs and, most important, could negatively impact the delivery of medicines.

In summary, we believe the proposed actions will ensure that Lakeland, Landover and all other McKesson DCs are able to identify and investigate excessive orders. McKesson has taken steps since 2005 to become more alert to dispensing issues as reflected in its response to the pharmacies you identified. Thus, a suspension at Lakeland is not necessary as a preventative measure and will have a significant adverse impact on distribution of prescriptions drugs. We can provide additional detail if needed.

McKesson has worked with DEA for more than 20 years on issues related to the distribution of controlled substances. The company is anxious to renew this relationship and hopes that the steps outlined above will be the basis for future cooperation.

We would like to discuss these actions with you as soon as possible. We will contact your office to arrange a meeting as soon as possible.



Counsel to McKesson Corporation